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MAR 26 2002

Mr. Miguel Reyes
President
Efficient Laboratories, Inc.
5565 N.W. 74th Avenue
Miami, Florida 33166

Dear Mr. Reyes:

This is in response to your letter of February 19, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Efficient Laboratories, Inc. is making the claims identified below for the product **Venoflash®**.

The product **Venoflash®** uses the claims "Promotes Leg Vein Health," "Helps Protect Against Leg Swelling," and "Helps Maintain Leg Vein Circulation." These claims are disease claims because they suggest that the product is intended to treat, prevent, or mitigate diseases, namely disorders of venous blood flow such as varicose veins. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1015-17), FDA stated that a claim to affect a characteristic sign or symptom of a disease is a disease claim. We stated that a reference to a physiological sign or symptom is an implied disease claim if the condition to be treated or prevented is a disease and the signs and symptoms referred to in the labeling, in context, are characteristic of a disease and thus create an inference that the product is intended to treat or prevent the disease (65 FR at 1017). Leg swelling is not a normal state of the body, nor are there "normal" amounts of swelling in otherwise healthy persons. Leg swelling is, however, a characteristic symptom of venous circulatory disorders of the leg that are diseases such as varicose veins. Therefore, in the context of the claims for your product that it "promotes leg vein health" and "helps maintain leg vein circulation," the statement that it "helps protect against leg swelling" clearly evidences that the product is intended to treat a consequence of abnormal conditions of venous circulation of the legs that are diseases.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to

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regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Handwritten signature of John B. Foret in cursive script.

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

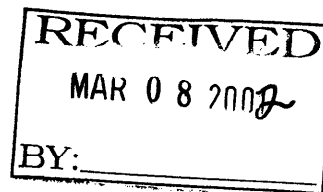
FDA, Florida District Office, Office of Compliance, HFR-SE240



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February 19, 2002

Office of Special Nutritionals
HFS-450
Center for Food Safety and Applied Nutrition
200 C Street
Washington, D.C. 20204



Subject: Notification - Venoflash® Forte

Dear Sir or Madam,

Pursuant to 21 CFR 101.93, this is my notification concerning Venoflash® Forte:

Name and Address of the distributor.

Efficient Laboratories, Inc.
5565 N.W. 74th Avenue
Miami, FL 33166

1. Text: ***Promotes Leg Vein Health *** Helps Protect Against Leg Swelling
*** Helps Maintain Leg Vein Circulation***.
2. Name of dietary supplement or ingredient. Venoflash® Forte containing Hawthorne Berries, Horse Chestnut Seed Extract, Hesperidan, Hamamelis Virginiana. Rutin and Vitamin C, E, B-1, Niacin, B-6 & B-12.

I certify that the information contained in this notice is complete and accurate, and that this firm has substantiation that the statement is truthful and not misleading.

Sincerely,

Miguel Reyes
President